Claims

1. An assembly adapted for bone, tissue and/or duct dilatation of a living being comprising in combination: a hollow tube; an inflatable and deflatable balloon element having proximal and distal ends in fluid communication with the hollow tube; and, balloon tensioning and/or balloon wrapping device(s) for stretching the balloon element and/or folding, pleating or wrapping the balloon element to facilitate insertion and/or removal of the balloon element through a narrow diameter duct, access channel or canula.

2. An assembly according to claim 1 wherein said balloon element is capable of being inflated to a working diameter of about 12 mm to about 25 mm.

3. An assembly according to claim 1 wherein said balloon element is capable of being inflated to a working pressure of about 200 – 400 psi over a relatively short balloon working length.

4. An assembly according to claim 1 wherein said balloon element is stretched and/or folded, pleated or wrapped to a diameter of about 4 – 5 mm or less for insertion through and/or removal from said duct, access channel or canula.

5. An assembly according to claim 1 wherein said balloon tensioning and/or balloon wrapping device(s) is/are selected from the group consisting of active and passive tensioning and wrapping devices.

6. An assembly according to claim 1 wherein, upon inflation to its working pressure, the balloon element maintains a high degree of puncture and abrasion resistance.

7. An assembly according to claim 1 wherein the balloon element is mounted on the distal end of the hollow tube, and the proximal end of the balloon element is bonded to or integrally connected with an end of the tube to create a passage through the tube to the interior of the balloon element.

8. An assembly according to claim 7 wherein the distal end of the balloon element is sealed, and the assembly further comprises a rod element running through the passage of the tube and the interior of the balloon element to the sealed distal end of the balloon element.

9. An assembly according to claim 8 wherein axial force can be applied manually or automatically to push the rod element against the sealed distal end of the balloon element causing tension and axial elongation of the balloon element.

10. An assembly according to claim 9 wherein the rod element is not attached to the balloon element.

11. An assembly according to claim 9 wherein the rod element is attached to or otherwise engages the balloon element.

12. An assembly according to claim 11 further wherein rotational force can be applied manually or automatically to rotate the rod element from its free-standing position causing the balloon element at least in part to wrap around the rod element.

13. An assembly according to claim 9 further wherein said rod element is spring loaded to apply axial tensioning and elongation to the balloon element.

14. An assembly according to claim 11 further wherein said rod element is spring loaded to apply rotational tensioning to the balloon element.

15. An assembly according to claim 11 further wherein said rod element is spring loaded to apply both automatic axial and rotational tensioning to the balloon element.

16. An assembly according to claim 9 wherein said rod element comprises a compressive or rotational spring element.

17. An assembly according to claim 7 wherein said hollow tube comprises a compressive spring element.

18. An assembly according to claim 1 wherein the balloon tensioning and/or wrapping device is hydraulically or pneumatically actuated.

19. An assembly according to claim 8 wherein said rod element is adjustable in length.

20. An assembly according to claim 1 further comprising elastomeric tubing placed over said balloon element.

21. An assembly according to claim 1 further wherein the exterior of said balloon element is coated with a material to improve puncture and abrasion resistance.

22. An assembly according to claim 11 further comprising at least a canula element wherein at least one end of the balloon element extends into or completely through said canula element when the balloon element is positioned in a cavity to be dilated.

23. An assembly according to claim 22 further wherein said canula element is adapted to restrict expansion forces of the balloon element during inflation.

24. An assembly according to claim 8 wherein, after the balloon element is inserted in a cavity to be dilated and inflated to working pressure for a sufficient period of time, the interior of the inflated balloon element is filled in situ with a cement material.

25. An assembly according to claim 24 wherein the rod element is removed before the balloon element is filled with a cement material.

26. An assembly according to claim 24 wherein the rod element has a hollow interior to act as a vent for working fluid while the balloon element is filled with a cement material, and is removed before the cement hardens.

27. An assembly according to claim 24 wherein the hollow tube is detached from the balloon element after the balloon element is filled with the cement material.

28. An assembly according to claim 1 wherein said balloon element comprises a multi-lumen balloon.

29. An assembly according to claim 11 wherein said rod element is spring loaded to apply automatic axial tensioning to the balloon element and is adapted for optional manual rotational tensioning of the balloon element.

30. An assembly according to claim 1 further comprising a pre-curved guidewire in the interior of the balloon element.

31. An assembly according to claim 8 wherein said rod element comprises concentric inner and outer tubular members which are rotatable relative to one another and said balloon element is attached to or engages one of said tubular members whereby rotational forces can be applied to cause the balloon element at least in part to wrap around one of said tubular members.

32. An assembly according to claim 8 further wherein said rod element is pre-curved and consists essentially of a material having memory properties.

33. An assembly according to claim 1 wherein said balloon element is pre-curved.

34. An assembly according to claim 1 wherein said balloon element consists essentially of a non-elastomeric material.

35. A method for treating a living being for bone, tissue and/or body duct dilatation comprising the sequential steps of: inserting an inflatable balloon element in an uninflated state into an interior region, cavity or passage of a damaged, collapsed or deformed bone, tissue or duct through a first narrow diameter opening or passageway to position the balloon element at a body location requiring dilatation; inflating the balloon element with a working fluid to a working pressure and for a time period sufficient to substantially completely dilate the interior region, cavity or passage to substantially

restore its normal size, shape and/or alignment; deflating the balloon element by withdrawing the working fluid; during and/or subsequent to said deflating step, stretching and/or folding, pleating or wrapping the balloon element to reduce its profile; and, withdrawing the previously-inflated balloon element through a narrow diameter opening or passageway, which may be the same as or different than said first narrow diameter opening or passageway.

36. A method according to claim 35 wherein said balloon element is inflated to a working diameter of about 12 mm to about 25 mm during the inflating step.

37. A method according to claim 35 wherein said balloon element is inflated to a working pressure of about 200 – 400 psi over a relatively short balloon working length during the inflating step.

38. A method according to claim 35 wherein said balloon element is stretched and/or folded, pleated or wrapped to a diameter of about 4 – 5 mm or less for the steps of inserting and/or withdrawing the balloon element.

39. A method according to claim 35 wherein said balloon element is stretched and/or folded, pleated or wrapped using at least a balloon tensioning and/or balloon wrapping device selected from the group consisting of active and passive tensioning and wrapping devices.

40. A method according to claim 35 wherein, following inflation to its working pressure, the balloon element maintains a high degree of puncture and abrasion resistance.

41. A method according to claim 35 further comprising the step of applying a vacuum to the inflated balloon element during the deflating step to assist with withdrawal of the working fluid.

42. A method according to claim 35 wherein the balloon element is mounted on the distal end of a hollow tube, and the proximal end of the balloon element is bonded to or integrally connected with an end of the tube to create a passage through the tube to the interior of the balloon element.

43. A method according to claim 42 wherein the distal end of the balloon element is sealed.

44. A method according to claim 43 further wherein a rod element passes through the tube and the interior of the balloon element to the sealed end of the balloon element.

45. A method according to claim 44 further comprising the step of applying axial force manually or automatically to said sealed end of the balloon element through

said rod element during and/or subsequent to the deflating step causing tension and axial elongation of the balloon element.

46. A method according to claim 45 wherein the rod element is not attached to the balloon element.

47. A method according to claim 45 wherein the rod element is attached to or otherwise engages the balloon element.

48. A method according to claim 47 further comprising the step of applying rotational force manually or automatically to said rod element during and/or subsequent to the deflating step causing the balloon element at least in part to wrap around the rod element.

49. A method according to claim 45 wherein said rod element is spring loaded to apply axial tensioning and elongation to the balloon element.

50. A method according to claim 48 wherein said rod element is spring loaded to apply rotational tensioning to the balloon element.

51. A method according to claim 35 wherein the balloon tensioning and/or wrapping device is hydraulically or pneumatically actuated.

52. A method according to claim 44 further wherein said rod element is adjustable in length, said method further comprising the step of adjusting the length of said rod element such that said rod element applies an axial tensioning to the balloon element during the deflating step.

53. A method according to claim 35 further comprising the step of coating the exterior of the balloon element with a coating to improve puncture and abrasion resistance.

54. A method according to claim 35 further wherein, upon inserting the balloon element into an interior region, cavity or passage, at least one end of the balloon element extends into or completely through a canula element positioned in one of the narrow diameter openings or passageways.

55. A method according to claim 35 wherein said balloon element comprises a multi-lumen balloon.

56. A method according to claim 47 wherein said rod element is spring loaded to automatically apply axial tensioning to the balloon element during the deflating step, said method further comprising the step of applying manual rotational tensioning to the balloon element during and/or subsequent to the deflating step.

57. A method according to claim 35 further comprising the steps of positioning a guidewire through the interior region, cavity or passage to be dilated, and using the guidewire to position the balloon element during the inserting step.

58. A method according to claim 57 wherein said guidewire is pre-curved.

59. A method according to claim 44 wherein said rod element is pre-curved and fabricated from a material having memory properties.

60. A method according to claim 35 wherein said balloon element is pre-curved.

61. A method according to claim 35 wherein said balloon element consists essentially of a non-elastomeric material.

62. A method for treating a living being for bone or tissue dilatation comprising the sequential steps of: providing a dilatation apparatus able to fit through a narrow opening, said dilatation apparatus comprising an inflatable balloon element in fluid communication with a hollow tube, and a rod element running through the interior of the hollow tube and the inflatable balloon element, wherein said balloon element is uninflated and is wrapped, folded, pleated or stretched at least in part about said rod element to reduce the profile of the balloon portion of the dilatation apparatus; inserting the dilatation apparatus into an interior region, cavity or passage of a damaged, collapsed

or deformed bone or tissue region through a first narrow diameter opening or passageway to position the balloon element at a body location requiring dilatation; inflating the balloon element through the hollow tube with a working fluid to a working pressure and for a time period sufficient to substantially completely dilate the interior region, cavity or passage to substantially its normal size, shape and/or alignment; and, filling the inflated balloon element in situ through the hollow tube with a cement material.

63. A method according to claim 62 comprising the further steps of removing the rod element before filling the balloon element with cement material and detaching the hollow tube from the balloon element after it is filled with cement.

64. A method according to claim 62 further wherein the rod element has a hollow interior which is used for venting working fluid from the balloon element while it is being filled with cement material.

65. A method according to claim 64 further comprising the steps of removing the rod element and detaching the hollow tube from the balloon element after it is filled with cement.

66. A method according to claim 62 wherein said balloon element is inflated to a working diameter of about 12 mm to about 25 mm during the inflating step.

67. A method according to claim 62 wherein said balloon element is inflated to a working pressure of about 200 – 400 psi over a relatively short balloon working length during the inflating step.

68. A method according to claim 62 wherein said balloon element is wrapped, folded, stretched and/or pleated about said rod element such that the balloon portion of the dilatation apparatus has a diameter of about 4 – 5 mm or less for the inserting step.

69. A method according to claim 62 wherein said balloon element comprises a multi-lumen balloon.

70. A method according to claim 62 further comprising the steps of positioning a guidewire through the interior region, cavity or passage to be dilated, and using the guidewire to position the balloon element during the inserting step.

71. A method according to claim 62 wherein said guidewire is pre-curved.

72. A method according to claim 62 wherein said rod element is pre-curved and fabricated from a material having memory properties.

73. A method according to claim 62 wherein said rod element is pre-curved and fabricated from a material having memory properties.

74. A method according to claim 62 wherein said balloon element consists essentially of a non-elastomeric material.

75. A method for treating a living being for dilatation of a section of a body duct to relieve a collapse or blockage condition comprising the sequential steps of: providing a dilatation apparatus able to fit through a narrow opening, said dilatation apparatus comprising an inflatable balloon element in fluid communication with a hollow tube, and a rod element running through the interior of the hollow tube and the inflatable balloon element, wherein said balloon element is uninflated and is wrapped, folded, pleated or stretched at least in part about said rod element to reduce the profile of the balloon portion of the dilatation apparatus; inserting the dilatation apparatus into a body duct to be dilated to position the balloon element at a duct section requiring dilatation; inflating the balloon element through the hollow tube with a working fluid to a working pressure and for a time period sufficient to substantially completely dilate the duct section to substantially its normal size; deflating the balloon element by withdrawing the working fluid; during and/or subsequent to said deflating step, stretching and/or folding, pleating or wrapping the balloon element to reduce its profile; and, withdrawing the dilatation apparatus including the previously-inflated balloon element from the treated duct.

76. A method according to claim 75 wherein said balloon element is inflated to a working diameter of about 12 mm to about 25 mm during the inflating step.

77. A method according to claim 75 wherein said balloon element is inflated to a working pressure of about 200 – 400 psi over a relatively short balloon working length during the inflating step.

78. A method according to claim 75 wherein said balloon element is stretched and/or folded, pleated or wrapped to a diameter of about 4 – 5 mm or less for the steps of inserting and/or withdrawing the balloon element.

79. A method according to claim 75 wherein said balloon element is stretched and/or folded, pleated or wrapped using at least a balloon tensioning and/or balloon wrapping device selected from the group consisting of active and passive tensioning and wrapping devices.

80. A method according to claim 75 further comprising the step of applying a vacuum to the inflated balloon element during the deflating step to assist with withdrawal of the working fluid.

81. A method according to claim 75 wherein the distal end of the balloon element is sealed, said method further comprising the step of applying axial force manually or automatically to said sealed end of the balloon element through said rod element during and/or subsequent to the deflating step causing tension and axial elongation of the balloon element.

82. A method according to claim 81 wherein the rod element is not attached to the balloon element.

83. A method according to claim 81 wherein the rod element is attached to or otherwise engages the balloon element.

84. A method according to claim 83 further comprising the step of applying rotational force manually or automatically to said rod element during and/or subsequent to the deflating step causing the balloon element at least in part to wrap around the rod element.

85. A method according to claim 81 wherein said rod element is spring loaded to apply axial tensioning and elongation to the balloon element.

86. A method according to claim 84 wherein said rod element is spring loaded to apply rotational tensioning to the balloon element.

87. A method according to claim 75 wherein the balloon tensioning and/or wrapping device is hydraulically or pneumatically actuated.

88. A method according to claim 75 wherein said rod element is adjustable in length, said method further comprising the step of adjusting the length of said rod

element such that said rod element applies an axial tensioning to the balloon element during the deflating step.

89. A method according to claim 84 wherein said rod element is spring loaded to automatically apply axial tensioning to the balloon element during the deflating step, said method further comprising the step of applying manual rotational tensioning to the balloon element during and/or subsequent to the deflating step.

90. A method according to claim 75 wherein said rod element comprises concentric inner and outer tubular members which are rotatable relative to one another, and said balloon element is attached to or engages one of said tubular members, said method further comprising the step of rotating said tubular members relative to one another during an/or subsequent to the deflating step to cause the balloon element to wrap at least in part around one of said tubular members.